## **EXHIBIT A**

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    Acting Under Authority Conferred By 28 U.S.C. § 515
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    Chief, Criminal Division
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10
                                UNITED STATES DISTRICT COURT
11
                             NORTHERN DISTRICT OF CALIFORNIA
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13
                                       SAN JOSE DIVISION
14
    UNITED STATES OF AMERICA,
                                                CASE NO. 18-CR-00258 EJD
15
          Plaintiff.
                                                STIPULATION AND [PROPOSED]
16
                                                SUPPLEMENTAL PROTECTIVE ORDER
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    ELIZABETH HOLMES and RAMESH
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    "SUNNY" BALWANI,
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          Defendants.
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          The United States of America, by and through ADAM A. REEVES, Attorney for the United
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    States Acting Under Authority Conferred by 28 U.S.C. § 515, and JEFF SCHENK, JOHN C. BOSTIC,
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    and ROBERT S. LEACH, Assistant United States Attorneys for the Northern District of California, and
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    the defendants, ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, and their attorneys,
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    KEVIN DOWNEY and LANCE WADE of Williams & Connolly for HOLMES, and JEFFREY B.
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    COOPERSMITH and STEPHEN A. CAZARES of Davis Wright Tremaine for BALWANI, hereby
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    stipulate and jointly request that the Court issue a supplemental Protective Order in this case as
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    described below.
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    [PROPOSED] SUPPLEMENTAL PROTECTIVE ORDER RE FDA AND CMS
    INFORMATION
    18-CR-00258 EJD
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The parties stipulated to, and the Court entered, a Protective Order in this case on or about July

1 2, 2018 (Docket #28) ("the Original Protective Order"). During the course of its investigation, the 2 3 United States has obtained materials from various government agencies, including the Food and Drug Administration ("FDA") and the Centers for Medicare & Medicaid Services ("CMS"), and may obtain 4 5 additional materials from the foregoing agencies or from other similar government agencies. These materials may contain information that the government considers confidential corporate information, 6 7 trade secrets, Protected Health Information (PHI, as defined in HIPAA), or protected by certain 8 privileges and doctrines, such as work product and deliberative process. Accordingly, the parties agree 9 that a Supplemental Protective Order is necessary to govern access to and use of such "Government Agency Documents," which shall include any documents produced by the government bearing a bates 10 number prefix containing "FDA" or "CMS" and bearing the legend "FDA/CMS – CONFIDENTIAL," 11 or any other documents the government identifies in writing as Government Agency Documents that are 12 13 in need of protection under the terms of this Supplemental Protective Order. Defendants agree to the 14 designation of documents as protected under this Supplemental Protective Order or the Original

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Therefore, the parties stipulate and agree as follows:

documents are worthy of such protection.

1. Each reference to "Private Documents" in paragraphs 1 through 4 and 6 of the Original Protective Order shall apply to Government Agency Documents.

Protective Order for the purpose of facilitating production of documents without delay caused by a need

for a line by line review of documents, and not based on any agreement or concession that any

## ADDITIONAL PROTECTIONS FOR PHI IN CMS DOCUMENTS

2. Pursuant to 45 C.F.R. § 164.512 et seq. and for purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and subject to the provisions of this Protective Order, legal counsel in this case, the employees and agents of each party, and all non-party Covered Entities, as that term is defined in HIPAA, are expressly and specifically authorized to use or disclose Protected Health Information (PHI), as that term is defined in HIPPA, in accordance with this order to:

- a) comply with the discovery obligations and requests made pursuant to the Federal
   Rules of Criminal Procedure in this case seeking PHI;
- b) request interviews or depositions and interview, depose, or respond in interviews or depositions in which PHI might be disclosed;
- c) prepare briefs and other materials for the Court so long as such materials are treated in accordance with this Protective Order; and
- d) disclose PHI to a party's expert regardless of whether the expert is a consulting or testifying expert.
- 3. The intent of the additional protections for PHI is to authorize the use and disclosure of PHI in accordance with 45 C.F.R. § 164.512 and the terms of this Protective Order. To the extent that the uses and disclosures of PHI authorized under this Protective Order may be permitted under other provisions of the HIPAA Privacy Rule, such uses and disclosures shall be made pursuant to and in accordance with 45 C.F.R. § 164.512(e). This paragraph shall not be read to authorize uses and disclosures of PHI that are not otherwise authorized under this Protective Order.
- 4. Pursuant to 5 U.S.C. § 552a(b)(11), this Protective Order authorizes CMS to release Privacy Act-protected information covered by this Protective Order, without the consent of the subject individual.

## CERTIFICATIONS AND MISCELLANEOUS

- 5. Prior to receiving access to any Government Agency Documents, each Defense Team member shall sign a copy of the attached Certification. By signing the Certification, each Defense Team member acknowledges that:
  - a) She or he has reviewed the Original Protective Order as well as this Order;
  - b) She or he understands the contents of those Orders;
  - c) She or he will access and use Government Agency Documents only as permitted by the terms of those Orders; and
  - d) She or he understands that failure to abide by those Orders may result in sanctions by this Court and she or he submits to the jurisdiction of the Court for the purpose

of enforcing those Orders and imposing any sanctions for their violation.

- 6. Defense counsel will maintain a copy of each signed Certification. The United States shall have no access to these signed copies without further order of the Court.
- 7. Any pleadings that reveal the contents of Government Agency Documents—either by attaching copies of such documents or by referencing their content—shall be filed under seal or redacted to prevent the disclosure of such contents.
- 8. Any disputes concerning this Stipulation and Protective Order shall be resolved by this Court only after defense counsel and counsel for the United States have first conferred and attempted to resolve the dispute.
- 9. Additionally, in the event either defendant seeks to challenge the designation of a document under this Supplemental Protective Order, or obtain a judicial ruling permitting broader disclosure of the contents of such a document, that defendant shall notify government counsel in this case to inquire whether the United States or any interested person or party objects to public disclosure of a specific document. Upon receipt of such notice, government counsel shall determine whether there is any objection to the requested lifting of protections under this Supplemental Protective Order for the identified document. Government counsel shall provide an email response to any such inquiries by defendants promptly, but no later than ten business days after receiving the inquiry, including identification of any requested redactions of the identified document. In the event government counsel fails to respond to such inquiry by defendants within 10 days, relief from the protections of this Supplemental Protective Order for the identified document shall be automatic.
- Documents at trial, the parties agree to meet and confer in advance of trial regarding appropriate procedures to protect sensitive information in such documents. By stipulating to this Supplemental Protective Order, the defendants do not waive any right they may have to petition the Court *ex parte* and *in camera* to challenge or remove the designation of a document under this Supplemental Protective Order, or the Original Protective Order, to facilitate the appropriate use of that document at trial. Conversely, the government does not concede that any such issues should be addressed *ex parte*.

1	11. Counsel for the defendants shall notify CMS of the completion of this case so that the		
2	agency can complete its disclosure tracking obligations. Such notification should be sent to		
3	DataUseAgreement@cms.hhs.gov and CMS counsel and a copy of this Order should be attached.		
4	12. The parties stipulate to this Order without prejudice to their ability to seek to modify the		
5	terms of the C	Order at a future date.	
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7	DATED: July	7 15, 2019	Respectfully submitted,
8			ADAM A. REEVES
9			Attorney for the United States Acting Under Authority Conferred
10			by 28 U.S.C. § 515
11			<u>/s/</u> JEFF SCHENK
12			JOHN C. BOSTIC
13			ROBERT S. LEACH Assistant United States Attorneys
14			
15	DATED: July	y 15, 2019	
16			
17			<u>/s/</u> KEVIN DOWNEY
18			LANCE WADE Attorneys for Elizabeth Holmes
			Attorneys for Enzaoeth Homies
19	DATED: July	15, 2019	
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21			/S/
22			JEFFREY B. COOPERSMITH STEPHEN A. CAZARES
23			Attorneys for Ramesh "Sunny" Balwani
24	SO ORDERE	ED.	
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26	DATED:		HONORABLE EDWARD J. DAVILA
27			United States District Court Judge
28	[PROPOSED] SUPPLEMENTAL PROTECTIVE ORDER RE FDA AND CMS INFORMATION 5		

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8	UNITED STATES DISTRICT COURT			
9	NORTHERN DISTRICT OF CALIFORNIA			
10	SAN JOSE DIVISION			
11	UNITED STATES OF AMERICA,	) CASE NO. 18-CR-00258 EJD		
12	Plaintiff,	) OUTPOOL OUTP		
13	v.	) WITH PROTECTIVE ORDER		
14	ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI,			
15	Defendants.			
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17	The undersigned acknowledges that she or he has received copies of the Original Protective			
18	Order (Dkt. No. 28) and the Supplemental Protect	tive Order in the case of UNITED STATES v.		
19	ELIZABETH HOLMES and RAMESH "SUNN"	Y" BALWANI, CR 18-258-EJD, and has read,		
20	understands, and agrees to the terms of both Orders, and hereby submits to the jurisdiction of the United			
21	States District Court for the Northern District of California for the purposes of enforcement of the terms			
22	and punishment of any violations thereof.			
23				
24	Date:			
25		Signature		
26		Printed Name		
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28	[PROPOSED] SUPPLEMENTAL PROTECTIVE ORDER RE FDA AND CMS INFORMATION 6 18-CR-00258 FID			